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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,874	09/30/2003	Howard Bernstein	17976-0006	6790
29052	7590	09/05/2006	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP 999 PEACHTREE STREET, N.E. ATLANTA, GA 30309				GEORGE, KONATA M
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/675,874	BERNSTEIN ET AL.
	Examiner Konata M. George	Art Unit 1616

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-56 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1-56 are pending in this application.

***Drawings***

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on January 15, 2004; April 16, 2004; August 2, 3004 and February 23, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the polymer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-7, 10-12, 14-21, 27, 30, 32-36, 38-48 and 50-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwards et al. (US 6,436,443).

Edwards et al. teach the delivery of porous particles to the pulmonary system.

Column 4, lines 15-25 teach that the diameter of the particles can range from 5 to 15 microns and that the particle density can be adjusted depending on the localized drug treatment area i.e. higher density particles can be used to upper airway delivery.

Column 5, lines 1-25 teach that the particles can be in the form of polymer particles wherein the polymers can those based on polyester such as polyglycolic acids or polylactic acid. Column 8, lines 35-57 teach examples of therapeutic agent which can be used in the particles such as antibiotics, proteins, etc. Column 7, lines 35-65 describe a method of making the particles. Column 8, lines 65-67 teach the formulation used for the treatment of asthma, emphysema or cystic fibrosis. Although, prior art reference of Straub et al. does not teach the delivery profile as claimed by applicant, it is the position of the examiner that this limitation is inherent with the formulation as claimed. The composition as claimed is directed toward porous microparticles comprising a pharmaceutical agent and a matrix material. Since there is no additional information with regards to the release profile (i.e. coating or physical makeup which

makes it a sustained released) any porous microparticle having the claimed drug and matrix material would have the release profile as claimed.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-11, 14-35 and 37-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub et al. (US 6,395,300).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Straub et al. discloses a porous drug matrix additionally comprising water-soluble polymers or sugars, wetting agents such as surfactants, etc. and the matrix having a diameter size of about 100 nm to 5 microns (col. 3, lines 46-61). Column 4, line 11 through column 8, line 9 list the types of drugs that can be employed in the drug matrix. Column 8, lines 34-67 teach examples of the polymers and sugars that can be used in the matrix such as polyvinylpyrrolidone (lines 41), xylitol (line 59) and lactose (line 63). Column 11, line 47 through column 12, line 33 teach a method of making the porous

drug matrix. Column 12, lines 46-67 teach examples of the surfactants to be employed in the matrix such as phospholipids like lecithins. Column 13, lines 29-41 teaches that the preferred embodiment of the invention is drug matrix in the form of a powder which can be reconstituted with an aqueous medium or using the powder formulation in a dry powder inhaler. Although, prior art reference of Straub et al. does not teach the delivery profile as claimed by applicant, it is the position of the examiner that this limitation is inherent with the formulation as claimed. The composition as claimed is directed toward porous microparticles comprising a pharmaceutical agent and a matrix material. Since there is no additional information with regards to the release profile (i.e. coating or physical makeup which makes it a sustained released) any porous microparticle having the claimed drug and matrix material would have the release profile as claimed.

### ***Conclusion***

6. Claims 1-56 are rejected.

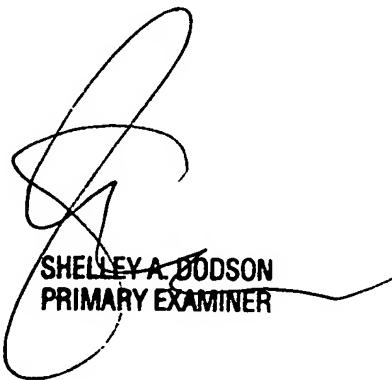
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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